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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,045	08/31/2001	Masahiro Sasaki	188-88	7829

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,045	SASAKI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims 7 mm 1-19-06

4)☒ Claim(s) *21-27, 29-32,34-39,and 49-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,29-32,34-39 and 49-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 October 2005 has been entered.

Claims 21-27, 29-32, 34-39, and 49-59 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The specification lacks a separate section of "BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)" for Figures 1-4.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer

program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections, Withdrawn

Objection of claim 51 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112,

The rejection of Claims 49, 50, 52, and 53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to "20,000" or "20,000 and 100,000" is withdrawn in view of applicant's persuasive arguments.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the claim has been amended to avoid confusion, but the limitation "extracted as a single protein from silk worm cocoons or raw silk" and "a purity of 90 % or higher" still exist in claim 51. As stated in the previous Office action, the specification at page 9, Preparation Examples 1, and 2 does not disclose the extracts being extracted as a single protein. It is not clear whether a single protein refers to purity or extraction method. If it refers to purity, then the purify of "90%" and "a single protein" in a single claim do not reconcile because "a single protein" implies there is nothing else but the protein but "90%" implies that there is other impurities. For the purpose of this Office action, the Office treats "90%" controls the scope of the claims. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claims 49, 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is maintained, because of the limitation "an average molecular weight range between 20,000 and 100,1000" in claims 49, and 50 and also the limitation "at least 20,000" in new claims 52, and 53.

Applicant argues that the adequate support is in the specification as originally filed. However, the specification as originally filed has support for making sericin of an

average molecular weight of either 100,100 (see the last sentence of Preparation Example 1 at page 9), or 20,000 (see the last sentence of Preparation Example 2 at page 9).

As for the new limitation "at least 20,000" in base claims 21, and 31, MPEP 2163.05 has the following guidelines:

> With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement. See also Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion"). Compare Union Oil of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232-33 (Fed. Cir. 2000) (Description in terms of ranges of chemical properties which work in combination with ranges of other chemical properties to produce an automotive gasoline that reduces emissions was found to provide an adequate written description even though the exact chemical components of each combination were not disclosed and the specification did not disclose any distinct embodiments corresponding to any claim at issue. "[T]he Patent Act and this court's case law require only sufficient description to show one of skill in the .. . art that the inventor possessed the claimed invention at the time of filing.").

The specification as originally filed does not have support for "at least 20,000", other than two points of an average molecular weight of either 100,000 or 20,000. Therefore, after consulting MPEP 2163.05, the Office concludes that the new limitation "at least 20,000" is a new matter.

The claims are also rejected for the limitation "extracted as a single protein". The Office is unable to find the support for this limitation.

Claim Rejections - 35 USC § 102

Claims 21-27, 29-31, 34, 36-39, 49-59 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,165,982 (Yamada et al).

Claims 21-27, 29-31, 34, 36-39, 49-59 are drawn to composition suitable for oral administration comprising water-soluble sericin powder with a purity of 90% or higher (base claims 21) in an effective amount to prevent colon cancer in a dose form, wherein claim 22-26, 36, 38, and 39 list the effect, functional characteristics, and/or intended uses of the active ingredient of said sericin, wherein claim 27 lists an intended use i.e., "in the form of a health supplement", wherein claims 29 and 34 list the dose ranges of 1 mg to 1 g per kg per body weight, wherein claim 30 and 37 list the source of sericin, and claims 49 and 50 list the range of average molecular weight being 20,000 and 100,000, claims 54-59 list sericin of the base claims to be having about 1-5% by weight in the preparation.

Applicant argues that Yamada et al., at most might render the claims obvious but fail to anticipate the claimed invention because Yamada et al., fail to suggest colon cancer prevention and fail to teach an effective amount of sericin/hydrolyzed product for preventing colon cancer. "Effective amount" has long been recognized as defining over prior art and does not constitute merely functional or intended use recitation.

These arguments have been fully considered but found unpersuasive. The instant claims are drawn to composition comprising sericin powder as the main active ingredient isolated from silkworm cocoons or raw silk, wherein the effective amount to prevent colon cancer in a dose form is "a daily dosage of 1 mg to 1 g per kg body weight in a dose form". As stated before in the previous Office actions, Yamada et al., at column 4, line 51 teaches "a dose of about 10 mg-100 g/day. Since average of adult human seems to from 49 kg to 89 kg (108-196 lbs, see Table 1) according to National

Health and Nutrition Examination Survey downloaded on 19 January 2006 from World Wide Web cdc.gov/nchs/data/nhanes/databriefs/adultweight.pdf, "10 mg-100 g/day" in Yamada et al., meet the limitation of "an effective amount to prevent colon cancer in a dose form" of the base claim 21. The preferred embodiment of the claimed dose for cancer prevention is "a daily dosage of 1 mg to 1 g per kg body weight in a dose form" (note the claim construction of the instant claims 21 and 29). Thus, "10 mg-100 g/day" in Yamada et al., must inherently be an effective amount to prevent colon cancer in a dose form. Note the instant specification at pages 11-20; the effects and/or functional characteristics as listed in the instant claim 22-26, 36, 38, and 39 are due to the inherent characteristics of the active ingredient of said sericin, In addition, Yamada et The preferred "about 0.5-5% by weight" of sericin at column 4 line 30 meets the limitation of instant claims 54-59, which covers 1-5% by weight of sericin in the preparation.

As for offer of the terminal disclaimer, the terminal disclaimer could not overcome 102(e) rejection.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-27, 29-32, 34-39, and 49-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making sericin powder

with molecular weight greater than 100 kDa with 90% purity or higher, does not reasonably provide enablement for making sericin powder with an average weight of 20 kDa. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is Aundue≅ include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The preferred embodiment of the claims is drawn to sericin of molecular weight of 20,000 Dalton with a purity 90% or higher.

Teramoto et al., (2005, Biosci. Biotechnol. Biochem., vol. 69, pages 845-847) at page 845, left column teach that three kinds of sericins exist: one greater than 250 kDa, about 180 kDa, and about 100 kDa. Takasu et al., (2002, Biosci. Biotechnol. Biochem., vol. 66, pages 2715-2718) at page 2716 teach at Table 1 several different sizes of sericin, but none has molecular weight of 20,000. In addition, Takasu et al. teach at page 2715, right column, first full paragraph "no effective separations of sericins was established", at the time of the publication, which is 2002, two years after the effective filing date of the instant application.

Considering the unpredictable state of art, limited guidance in specification how to make the instantly claimed invention, it is concluded that undue experimentation to practice the full scope of the claimed invention.

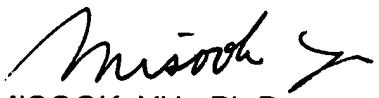
Conclusion

All other previously rejected claims not repeated here in this Office action is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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